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Visible Spectrophotometric determination of Valacyclovir by using Aradimethylaminocinnamaldehyde Reagent

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Abstract: A simple, precise, selective, accurate and economical method have been developed by using PDAC reagent for the quantitative estimation of valacyclovir in bulk and its pharmaceutical formulations. The presence of free amino group in valacyclovir enables the condensation reaction with paradimethylamino cinnamaldehyde (PDAC). The orange red coloured complex is obtained due to the formation of shiff's base. It exhibits the absorption maxima at 524nm and obeying beer's law in the concentration range of 10-100µg/mL respectively. The results of the analysis have been validated statistically and by recovery studies. This method is used for the routine analysis of VAL
Key words: valacyclovir, PDAC, tablet dosage form, orange red colour complex.

Introduction

It is chemically {L-valine-2-[(2-amino-1,6-dihydro-6-oxo-9-hipurin-9-yl)methoxy] ethyl ester}. Valaciclovir is phosphorylated by viral thymidine kinase to acyclovir triphosphate (the active metabolite) which then inhibits herpes viral DNA replication by competitive inhibition of viral DNA polymerase, and by incorporation into and termination of the growing viral DNA chain. Literature survey reveals that the quantitative determination of drug is determined by using various UV spectrophotometric methods[1-4] and High performance liquid chromatographic methods[5-8] and some visible methods[9]. No visible spectrophotometry reported by using PDAC reagent. Hence, the present work deals with the estimation of valacyclovir by using PDAC reagent in hydrochloric acid in bulk and its pharmaceutical formulations. The entire drug valacyclovir information is taken in drug bank[11] and validation done according to ICH guidelines[10].

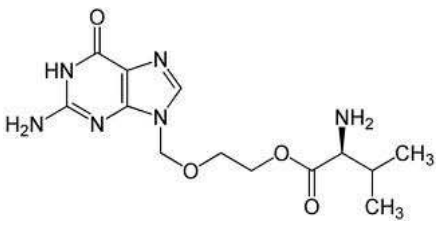

Figure 1 : Structure of Valacyclovir

Experimental Section

Valacyclovir working standard (99.85%) was obtained from Hetero Drugs Pvt Ltd, Hyderabad, India.

Chemicals and reagents

The reagents and chemicals used were-

1) Bulk drug, valacyclovir
2) PDAC reagent
3) Distilled ethanol
4) Distilled water

Instrumentation

A schimadzu double beam spectrophotometer with 1cm matched glass cells was used for all spectral measurements.

Preparation of standard

Accurately weigh 100mg of valacyclovir and was dissolved in 40mL of distilled water and further diluted with sufficient quantity of distilled ethanol (i.e.,1000µg/mL). Further dilution was made with distilled ethanol to get the final concentration of 100µg/ml.

Preparation of sample

For the estimation of valacyclovir,5 tablets were weighed and triturated to fine powder.Tablet powder equivalent to100mg was weighed, dissolved in 40mL distilled water and further diluted with sufficient quantity of distilled ethanol. This was then filtered through whatmann filter paper no.41 to get the concentration of 100µg/mL. Further dilution was made to get the concentration of 10µg/mL and was determined at 524nm.

Preparation of PDAC reagent

Alcoholic 0.5% PDAC reagent was prepared by dissolving 0.5gm of PDAC reagent in 100mL of distilled ethanol.

Method

Fresh aliquots of valacyclovir ranging from 1 to 10mL (1mL=100µg/mL) were transferred into a series of 10mLvolumetric flasks to provide final concentrations of 10-100µg/mL. To each flask, 1mL of alcoholic PDAC (0.5%) solution and two drops of conc.HCl were heated at 40^0C for 20min. The solutions were cooled to room temperature and made upto mark withdistilled ethanol. The absorbance of orange red coloured chromogen was measured at 524nm against the blank. The amount of valacyclovir present in the sample was computed from its calibration curve. The beer's plot was shown in figure 2.

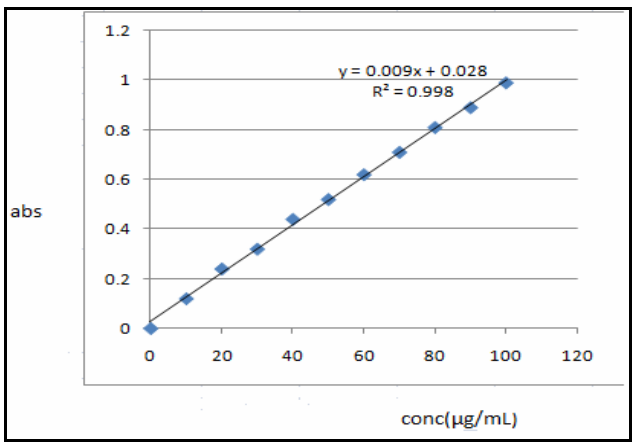

Figure 2 : beer's law limit for valacyclovir

Method Validation

The developed method was validated for its accuracy, precision, reproducibility and selectivity.The accuracy of the method was determined by performing recovery studies on tablet formulation and for prepared solutions containing known amount of drug by standard addition method in which preanalyzed samples were taken and standard drug was added at three different levels. Also, the experiment was repeated three times in a day to determine intraday precision and on three different days to determine interday precision. The %RSD was calculated at each concentration level and the results were given in table 3. The reproducibility was confirmed by repeating the method by three different analysts and the %RSD was alculated. The selectivity of the method was checked by monitoring a standard solution of VAL in presence of other compounds of tablets.

Results and Discussion

The optical characteristics such as beer's limit, molar extinction coefficient, %RSD, LOD, LOQ were calculated and shown in table1.Commercial formulation of valacyclovir was successfully analyzed by proposed method and the results are represented in table 2. To evaluate validity and reproducibility of the methods, fixed amount of drug were added to the preanalyzed formulation. The results of % recovery are summarized in table 4. There is no interference of additive and excipients in proposed analytical methods. The proposed spectrophotometric method for the estimation of valacyclovir are simple, sensitive, accurate and precise and can be used for the quality control of this drug in bulk as well as in pharmaceutical formulations.

Table 1: Optimum conditions, optical characteristics & colour development of VAL by using PDAC reagent

λmax	524nm
Beer's limit (µg/mL)	10-100
Amount of colouring agent (mL)	1
Absorption maxima (nm)	524
Molar absorptivity (lit/mol/cm)	12×10^{-3}
Correlation coefficient (r)	0.998
Regression equation * (y = mx + c)	Y = 0.009x + 0.028
Slope(m)	0.009
Intercept(c)	0.028
Accuracy indicated by % recovery	100.71%
Precision (% relative standard error)	0.65
LOD(µg/mL)	0.42
LOQ(µg/mL)	1.26

*y=mx+c,where x is the concentration in (µg/mL) and y is the absorbance unit (ΔA)

Table 2 : Analysis of tablet formulation

Label claim (mg)	Amount found (n=6)	% recovery	%RSD
500 mg	10	99.98%	0.02

Table 3: Precision data

Intra day			**Inter day**		
Amount taken	**Amount taken ± SD**	**% RSD**	**Amount taken**	**Amount taken ± SD**	**% RSD**
10	9.99 ± 0.01	0.63	10	9.97 ± 0.07	0.62
20	19.97 ± 0.05		20	1.95 ± 0.03	
30	28.48 ± 0.04		30	3.72 ± 0.02	

Table 4: Results of % recovery in tablet formulation

Formulation	Estimation of VAL in tablet formulations			% recovery of valacyclovir				
	Label claim (mg)	Amount found(mg)	% RSD	% of drug added	Concentration(g/mL)		% of drug recovered	% RSD
					Pure drug	formulation		
Valacyclovir tablets	5	4.91	0.6	50%	10	10	97.5	0.87
	5	4.89		100%	15	10	100.4	0.62
	5	4.85		150%	20	10	104.25	0.43

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